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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,047	01/14/2004	Heinrich Kladders	1/1449	4842

28501 7590 04/17/2007

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	PAPER NUMBER
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,047	KLADDERS ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/04.1/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. US 5,152,284.

As to claim 1, Valentini teaches a method for administering a composition by inhalation comprising administering to a patient the composition, contained in a capsule (fig.1, 22) comprising a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis (see fig.1) and which is intended to accommodate the composition in the form of a powder (col.1, lines 40-50), in a powder inhaler (fig.1, 10), wherein the features forming the outer contour of the capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis (see capsule 12 in fig.1), the following features being excluded from the conditions of symmetry: fine structures of the seams which are produced by the sealing of the seams of the indiyidual parts of the capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or angles of taper up to 5° (see fig.1, 12). Valentini however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 1. Thus, the method steps as cited in claim 1 would have been obvious result of using the apparatus of Valentini.

As to claim 2, Valentini teaches the method according to claim 1 wherein the inhaler is a Bernoulli inhaler. Applicant on page 3, lines 26-28 of his disclosure states that powder inhaler operate by the Bernoulli effect, which behave identically irrespective of their positioning. Since Valentini also teaches a powder inhaler, the inhaler of Valentini is considered Bernoulli inhaler.

As to claim 3, Valentini teaches the method according to claim 1 wherein features located on the outer contour of the capsule surface and forming a symmetrical pair may have a tolerance and inaccuracy deviating from the symmetry of 0.15 mm in each case (see fig.1, 22).

As to claim 4, Valentini teaches the method according to claim 1 wherein the capsule has elevations on its outer surface (see labeled fig.1, attachment below).

As to claim 5, Valentini teaches the method according to claim 1 wherein the capsule has no elevations (fig.1 depicts that capsule 22 has no elevations in at least a portion of its outer surface).

As to claim 6, Valentini teaches the method according to claim 1 wherein the capsule consists of two parts (see labeled fig.1, attached below) which can be pushed telescopically one inside the other along the longitudinal axis (fig. 1 of Valentini clearly depicts two parts of capsule (22) pushed telescopically).

As to claim 7, Valentini teaches the method according to claim 1 wherein the capsule has a cylindrical outer contour (see fig.1, 22).

As to claim 8, Valentini lacks the explicit teaching of wherein the capsule has tapering sealed ends. However, it should be noted that Valentini teaches a capsule where an upper and lower parts are sealingly engaged (see labeled fig.1, attached below) by the nature of upper and lower parts' diameter sizes. The narrower diameter upper part (part I, see labeled fig.1, attached below) of capsule 22 is considered tapering sealed end. Thus Valentini teaches wherein the capsule has tapering sealed ends.

As to claim 9, Valentini teaches the method according to claim 6 wherein the seam created between the two parts of the closed capsule is offset from the center by 0 to 12% of the outer longitudinal length (see labeled fig.1, attached below).

As to claim 10, Valentini teaches the method according to claim 1 wherein the capsule comprises a member of the D- symmetry group in terms of its outer contour, irrespective of the seam between the two parts of the capsule and irrespective of any manufacturing tolerances (see labeled fig.1, attached below).

As to claim 17, Valentini teaches a capsule (fig.1, 22) for holding a pharmaceutical composition which, in the closed state, has a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis (see fig.1, 22) and which consists of two parts which can be pushed telescopically inside one another along the longitudinal axis (see labeled fig.1, attached below), wherein the features forming the outer contour of the closed capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis, the following features being excluded from the conditions of symmetry (see labeled fig.1, attached below): fine structures of the seams which are produced by the sealing of the seams of the individual parts of the capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or angles of taper up to 5° (see "elevation" in the labeled fig.1, attached below).

As to claim 18, Valentini teaches the capsule according to claim 17 wherein the seam created between the two parts when the capsule is closed is offset from the center by 0 to 12% of the outer longitudinal length (see labeled fig.1, attached below).

As to claim 19, Valentini teaches the method according to claim 1 wherein the capsule comprises a member of the D- symmetry group in terms of its outer contour, irrespective of the seam between the two parts of the capsule and irrespective of any manufacturing tolerances (see labeled fig.1, attached below).

As to claim 20, Valentini teaches the capsule according to claim 17 wherein features located on the outer contour (see labeled fig.1, attached below) of the capsule surface and forming a symmetrical pair may have a tolerance and inaccuracy deviating from the symmetry of 0.15 mm in each case (see labeled fig.1, attached below).

Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. US 5,947,118

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As to claim 11, Hochrainer in figure 6 teaches the method according to claim 1 wherein the inhaler comprises two housing parts, an upper housing part (13) which is connected to a mouthpiece (12), and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening connected to the mouthpiece via a connection capable of conducting an aerosol, powder or liquid (col.3, lines 1-17). Hochrainer however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 11. Thus, the

method steps as cited in claim 11 would have been obvious result of using the apparatus of Hochrainer.

As to claim 12, Hochrainer teaches the method according to claim 11 wherein the capsule chamber has a cross section 1.1 to 2.5 times as great as the capsule diameter and a length 1.02 to 2 times the length of the capsule (see three capsules depicted in figure 6).

As to claim 13, Hochrainer teaches the method according to claim 11 wherein the inhaler has a cutting device (see "needles" in col.3, lines 5-7) comprising at least two sharp spikes and/or cutters (see "needles" in col.3, lines 5-7), the spikes and/or cutters being capable of breaching the capsule chamber(s) (col.3, lines 7-10).

As to claim 14, Hochrainer teaches the method according to claim 11 wherein the inhaler comprises: a) a cup-shaped lower part open at the top (6), b) a plate (8) which covers the opening of the lower part and perpendicularly to which is formed a pharmaceutical capsule chamber of the type described above (see capsules depicted in fig.6), a button (10) movable counter to a spring (11) on the capsule chamber, a cutting device (see "needles" in col.3, lines 5-10) comprising two sharp spikes or cutters for opening the capsule (col.3, lines 5-10), c) an upper part (13) with the mouthpiece which is connected to the capsule chamber so as to be able to convey a powder, aerosol or liquid, and d) a lid (15), the elements a), b) c) and d) being joined together by a common hinge element (see hinge apertures on the body of cap 15 and lower part 6 in fig.6) such that they can be moved back and forth relative to one another.

As to claim 15, Hochrainer teaches the method according to claim 11 wherein inhaler contains a magazine of capsule chambers (1).

As to claim 16, Hochrainer teaches an inhaler (fig.6) for administering a composition comprising an upper housing part (13) which is connected to a mouthpiece (12) and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening (opening though the mouthpiece) connected to the mouthpiece, wherein at least one capsule chamber is capable of accommodating a capsule having a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis wherein a composition is placed (see fig.6), the features forming the outer contour are symmetrical with respect to a transverse plane that bisects the longitudinal axis, the following features being excluded from the conditions of symmetry: fine structures of the seams which are produced by the sealing of the seams of the individual parts of the pharmaceutical capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or -angles of taper up to 5° (see fig.6). Hochrainer however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 16. Thus, the method steps as cited in claim 16 would have been obvious result of using the apparatus of Hochrainer.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "18" has been used to designate both air inlet/inhalation channel (see specification page 20, line 19) and button (see specification page 31, line 31). Corrected drawing

sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: specification lacks adequate description of figure 3d. Appropriate correction is required.

Claim Objections

Claims 1 and 18 are objected to because of the following informalities: as to claims 1 and 18, seam in line 8 lacks antecedent basis. Appropriate correction is required.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kladders (US 4,889,114) is cited to show powder inhaler.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/27/2007

Shumaya B. Ali
Examiner
Art Unit 3771

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3/30/07